UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

DEFENDANT'S MOTION IN LIMINE TO BAR EVIDENCE OR ARGUMENT RELATING TO ALLEGED FAILURE TO TEST

PRELIMINARY STATEMENT

In their lawsuits against Defendant Eli Lilly and Company ("Lilly"), Plaintiffs allege that Lilly failed to adequately warn their prescribing physicians of certain possible risks related to discontinuation of Cymbalta (duloxetine). Under Virginia law, evidence or argument that Lilly failed to adequately test Cymbalta has no bearing on Plaintiffs' failure-to-warn claims. The Virginia Supreme Court and this Court have held that litigation of a failure-to-warn claim focuses squarely on what the defendant had a *reason to know* based on the state of the existing science during the relevant time period — and *not* on what it *should have known* through the design and conduct of additional (or different) tests or studies. For this reason, Virginia law does not permit a plaintiff to prove or argue that the defendant could (or should) have conducted additional (or different) testing of its product beyond what FDA required to secure the medicine's approval. Such failure-to-*test* evidence is irrelevant to a failure-to-*warn* claim and must therefore be excluded.

Throughout the course of discovery and pre-trial proceedings in these cases, Plaintiffs have repeatedly signaled that they intend to introduce evidence and argue that Lilly could (and should) have conducted hypothetical additional studies of Cymbalta — the results of which are entirely speculative — and/or that it should have designed its existing studies to include additional hypothetical testing related to discontinuation symptoms. Because evidence of this kind is irrelevant to the failure-to-warn claims at issue, and is therefore inadmissible, Lilly moves *in limine* to exclude it from the upcoming trials in these cases.

BACKGROUND

The principal question in these failure-to-warn lawsuits is straightforward: whether Lilly adequately warned Plaintiffs' prescribing physicians of symptoms that might arise during discontinuation of Cymbalta. Under well-settled Virginia law, this inquiry is limited to whether

Lilly adequately warned of what it had *reason to know*, based on the *existing* state of the science, regarding discontinuation symptoms. *See Owens-Corning Fiberglas Corp. v. Watson*, 413 S.E.2d 630, 634-35 (Va. 1992). Virginia law did *not* impose on Lilly an obligation to warn of information it might have obtained through hypothetical additional (or different) testing or studies of Cymbalta that FDA did not require as part of the medicine's approval process. *See Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 569, 572-73 (E.D. Va. 2010). Indeed, before Cymbalta came to market, Lilly conducted dozens of clinical trials for Cymbalta and subjected them to FDA's rigorous review process. Throughout the medicine's pre-marketing review, FDA did not question the sufficiency of Lilly's testing — including its testing pertaining to discontinuation-emergent adverse events — and FDA ultimately approved Cymbalta based on its review of Lilly's careful study of the medicine. *See, e.g.*, FDA Medical Review No. 3 for Cymbalta (Duloxetine), Aug. 16, 2002 at 3-6, Ex. 1 to the Declaration of Jeffrey T. Bozman ("Bozman Decl."), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021427_s000_Cymbalta_Medr_P2.pdf (one of many documents describing FDA's review and approval of Lilly's pre-marketing studies of Cymbalta's efficacy and safety). Virginia law did not require Lilly to supplement this comprehensive, FDA-approved study protocol with hypothetical additional (or different) testing.

Notwithstanding these legal principles, Plaintiffs have signaled throughout pre-trial proceedings that they intend to introduce evidence and argue that Lilly should have conducted additional clinical trials for Cymbalta and/or included additional tests in the trials it conducted as part of the FDA approval process. Plaintiffs' exhibit list and deposition designations are replete with evidence that relate solely to Plaintiffs' theory that Lilly should have conducted additional

or different testing of Cymbalta. A few examples from the depositions of current and former Lilly employees demonstrate Plaintiffs' intent:

- In their deposition of Dr. Michael Detke, Lilly's former medical director for Cymbalta, Plaintiffs suggested in their questioning that Lilly should have used an elicited symptom checklist — as opposed to patient responses to open-ended questions — to further test the incidence of discontinuation-emergent adverse events in Cymbalta patients.[1] *See* Apr. 28, 2015 Detke Dep. Tr. at 78:3-80:6, 94:15-104:15, Bozman Decl. Ex. 2; CYM-02806828 to 02806829, Bozman Decl. Ex. 4.

- Also in their deposition of Dr. Detke, Plaintiffs introduced e-mail communications in which Lilly employees discussed the possibility of conducting additional clinical trials comparing tapered discontinuation of Cymbalta to abrupt discontinuation of the medicine. *See* Apr. 28, 2015 Detke Dep. Tr. at 186:14-201:10, Bozman Decl. Ex. 2; CYM-01873414 to 01873416, Bozman Decl. Ex. 5. Through their questioning, Plaintiffs suggested that Lilly should have conducted additional tapering studies beyond those conducted pursuant to FDA oversight to obtain approval of the medicine. *See* Apr. 28, 2015 Detke Dep. Tr. at 195:11-201:10, Bozman Decl. Ex. 2.[2]

- In their deposition of Dr. Madelaine Wohlreich, a Lilly clinical research physician, Plaintiffs again suggested through their questioning and introduction of e-mail exhibits that Lilly should have conducted additional tapering studies. *See generally* Apr. 29, 2015 Wohlreich Dep. Tr. at 92:3-131:10, Bozman Decl. Ex. 6; CYM-01873414 to 01873416, Bozman Decl. Ex. 5.

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[1] As Dr. Detke explained in his deposition, use of an elicited symptom checklist involves specifically asking a participant in a clinical trial if he or she experienced one or more symptoms on a pre-defined checklist. *See* Apr. 28, 2015 Detke Dep. Tr. at 96:6-15, Bozman Decl. Ex. 2. When such a checklist is *not* used, clinicians instead ask patients to describe any symptoms they experienced — without prompting the patients with specific symptoms from a list. *See id.* at 78:3-14. As Dr. Detke noted, each of these two approaches has pros and cons, and neither is necessarily more effective than the other. *See id.* at 97:3-15, 100:18-102:25. Dr. Detke also explained that use of elicited symptom checklists can increase false positives and make it more difficult to discern differences between drug and placebo. *See id.* at 97:3-15. Moreover, certain scientific literature confirms that the open inquiry approach used in the Cymbalta trials can be "more effective in distinguishing drug effect from placebo than the solicited approach." Wernicke et al., *Detecting Treatment Emergent Adverse Events in Clinical Trials*, 28 Drug Safety 1057, 1057 (2005), Bozman Decl. Ex. 3.

[2] In response to Plaintiffs' counsel's suggestion that Lilly did not sufficiently assess tapered discontinuation, Dr. Detke explained that the company did in fact conduct a double-blind study that specifically compared abrupt discontinuation to tapered discontinuation and that the study showed some benefit to tapering. *See* Apr. 28, 2015 Detke Dep. Tr. at 197:1-20, 198:2-13, Bozman Decl. Ex. 2.

Plaintiffs' intent to introduce failure-to-test evidence and argument is even more apparent in their opposition to Lilly's motion for summary judgment, which is almost entirely based on irrelevant arguments that Lilly should have conducted additional testing of Cymbalta. For example:

- "Lilly also *avoided studying withdrawal effects using the methodology Lilly cultivated for Prozac* out of fear that bad data about Cymbalta would 'end up in the label.'" Pls.' Opp'n to Def.'s Mots. for Summ. J., July 10, 2015 (Dkt. No. 133 (*Ali*)), Dkt. No. 121 (*Hagan-Brown*)) at 1 (emphasis added).

- "[E]ven though Lilly developed and promoted a specific methodology for measuring discontinuation symptoms using a discontinuation checklist for Prozac, *Lilly did not use that system in assessing withdrawal for Cymbalta*." *Id.* at 14 (citing e-mail communications regarding symptom checklists) (emphasis added).

- "*Lilly never systematically measured withdrawal reactions beyond two weeks*, even though most patient's [sic] withdrawal lasted longer than two weeks." *Id.* at 14-15 (citing e-mail communications and deposition testimony regarding durations of study periods) (emphasis added).[3]

- "[Dr. Perahia] specifically proposed conducting clinical trials to develop evidence-based medical recommendations. . . . *Lilly, however, never went about conducting such trials — never studied withdrawal beyond two weeks and avoided using a checklist to measure withdrawal reactions*." *Id.* at 29 (citations omitted) (emphasis added).

- "*Lilly never attempted to study withdrawal longer than two weeks*, even though their studies showed that most withdrawal lasted past two weeks." *Id.* at 29-30 (citations omitted) (emphasis added).

All of these critiques by Plaintiffs are inadmissible. And they, of course, are entirely speculative as well. Although Plaintiffs' brainstorming has produced examples of additional testing that Lilly theoretically could have conducted — e.g., use of elicited scales or discontinuation symptom checklists, longer discontinuation studies, and examination of different

[3] Regarding Plaintiffs' criticism that Lilly should have conducted a four-week tapering study, Dr. Detke explained that the tapering benefit observed in the two-week study indicated that further study of tapering duration would likely not yield significant additional information. *See* Apr. 28, 2015 Detke Dep. Tr. at 198:2-13, Bozman Decl. Ex. 2.

tapering schedules — Plaintiffs have *never* come forward with any evidence showing what the results of such hypothetical testing would have been, how the results would have impacted Lilly's warnings for Cymbalta, and/or how any resulting change in the warnings would have impacted the prescribing decisions of Plaintiffs' physicians. In short, Plaintiffs have failed to demonstrate how their imagined additional testing has any non-speculative connection to their claims in these cases brought under Virginia law.

In any event, Plaintiffs' intent is clear and undisputed: Plaintiffs will attempt to introduce evidence and argue that Lilly could (or should) have (1) used elicited scales or discontinuation symptom checklists in its clinical trials for Cymbalta; (2) conducted additional (or different) clinical trials to assess discontinuation-emergent adverse events beyond two weeks post-discontinuation; (3) conducted additional (or different) studies to assess the benefits of tapering or certain tapering schedules, including studies comparing abrupt versus tapered discontinuation; (4) conducted additional (or different) studies comparing discontinuation symptoms in Cymbalta patients with patients taking other medicines, including Prozac, Paxil, and Effexor; and/or (5) conducted additional (or different) studies assessing other doses of Cymbalta.[4] For the reasons that follow, such evidence is irrelevant to Plaintiffs' claims and must therefore be excluded.

ARGUMENT

I. Failure-to-Test Evidence Is Irrelevant and Therefore Inadmissible.

Pursuant to well-settled case law in Virginia, evidence of alleged failure to test is irrelevant to a failure-to-warn claim and therefore inadmissible. *See Torkie-Tork v. Wyeth*, 757

[4] Any evidence or argument that Lilly should have studied other doses of Cymbalta would also be subject to exclusion under the Court's prior order dismissing Plaintiffs' design defect claims. *See* Order Granting Lilly's Motion for Judgment on the Pleadings, May 1, 2015 (Dkt. No. 83 (*Ali*)), Dkt. No. 79 (*Hagan-Brown*)).

F. Supp. 2d 567, 573 (E.D. Va. 2010) (attached at Bozman Decl. Ex. 7); *see also* Fed. R. Evid. 401 (evidence is not relevant if it is not "of consequence in determining the action"); Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). For this reason, the Court should issue an order precluding Plaintiffs from introducing evidence showing — or from arguing — that Lilly could or should have conducted hypothetical additional (or different) testing of Cymbalta.

Under Virginia law, a products liability claim may take one of only three forms: defective manufacturing, defective design, or failure to warn. *Torkie-Tork*, 757 F. Supp. 2d at 571-72 (citing *Morgen Indus., Inc., v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996)). Accordingly, courts have consistently held that a plaintiff may not bring a claim for failure to test in Virginia. *See Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 506 (E.D. Va. 2013) ("No [Virginia] court has yet accepted a 'failure to test' theory as a viable claim separate and apart from the three traditional product defect claims . . . . Any claim based on a 'failure to test' theory, therefore, must be dismissed, with prejudice."), *aff'd*, 587 F. App'x 78 (4th Cir. 2014); *Sykes v. Bayer Pharm. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (rejecting failure-to-test claim on grounds that it did not constitute one of three recognized products liability claims under Virginia law: "By implication, any other type of product-liability claim cannot succeed."); *see also Sutherlin v. Lowe's Home Ctrs., LLC*, 2014 WL 7345893, at *8 (E.D. Va. Dec. 23, 2014) ("Numerous [Virginia] courts have rejected attempts to expand the universe of cognizable negligence claims in products liability beyond those for design, manufacture and failure to warn." (citing *Torkie-Tork*, 757 F. Supp. 2d at 571)). Indeed, Plaintiffs here have previously conceded that Virginia does not recognize a failure-to-test cause of action. *See* Pls.' Opp'n to Def.'s Mots. for Summ. J., July 10, 2015 (Dkt. No. 133 (*Ali*)), Dkt. No. 121 (*Hagan-Brown*)) at 14 n.6 (conceding that "there is no recognized 'failure to test' cause of action" in Virginia).

Furthermore, Virginia law is clear that a plaintiff in a products liability case may not introduce failure-to-test evidence (or argument) in support of a failure-to-warn claim. *See Torkie-Tork*, 757 F. Supp. 2d at 572-73. In *Torkie-Tork*, this Court oversaw a lawsuit in which a woman claimed that the defendant pharmaceutical manufacturer (Wyeth) had failed to adequately warn her prescribing physicians of the risk of breast cancer associated with Prempro, a hormone therapy medicine. *See id.* at 568, 570. In support of her failure-to-warn claim, the plaintiff sought to introduce evidence showing that the defendant should have conducted further studies of Prempro's alleged association with breast cancer "to ascertain the nature of the risk and to warn doctors accordingly." *See id.* at 571. This Court rejected this tactic, holding that, under Virginia law, a plaintiff may not seek to bolster a failure-to-warn claim by introducing evidence showing that a pharmaceutical manufacturer could have conducted additional testing beyond what FDA required for the medicine's approval. *See id.* at 569 (holding that Virginia law "imposes no duty on a manufacturer to conduct additional studies or tests of its products"); *id.* at 572-73 (concluding that Wyeth did not have "a duty to conduct additional studies of Prempro beyond those required by the FDA"). Accordingly, in *Torkie-Tork*, this Court excluded all evidence and argument regarding Wyeth's alleged failure to test. *Id.* at 573 ("[E]vidence and testimony [are] not admissible for the purpose of establishing that Wyeth could have or should have conducted additional tests of Prempro, and counsel must not be permitted to advance arguments in this regard.").

In reaching this conclusion, this Court explained that, pursuant to decisions of the Supreme Court of Virginia, the state imposes a *reason-to-know* standard in products liability cases, which means that the manufacturer's duty to warn is limited to what it knew or had reason to know based on the state of the science as it existed when the product left the manufacturer's

control — and *not* on how the science might (or should) have existed if the manufacturer had conducted further testing. *See id.* at 572-73 (citing and discussing *Owens-Corning Fiberglas Corp. v. Watson*, 413 S.E.2d 630, 634-35 (Va. 1992)). This Court contrasted this standard with a *should-have-known* standard, which — though not recognized in Virginia — might require a manufacturer to take additional steps (such as further testing) to investigate a product's potentially dangerous properties. *See Torkie-Tork*, 757 F. Supp. 2d at 572-73 (citing *Watson*, 413 S.E.2d at 634-35).[5] In light of this distinction, this Court concluded that Virginia's reason-to-know standard precluded the plaintiff from introducing any evidence that the defendant could (or should) have conducted additional testing of Prempro to assess breast cancer risk. *See Torkie-Tork*, 757 F. Supp. 2d at 573. This Court also noted that, in the pharmaceutical context, "imposition of the reason-to-know standard is particularly sensible given the FDA already requires testing of any drug as a qualification for approval." *Id.*; *see also Ball*, 963 F. Supp. 2d at 506 (noting that, under Virginia law, a manufacturer does "not have a duty to conduct additional testing of its product beyond what was performed as part of the FDA approval process").

Applying these principles here, Plaintiffs must be precluded from introducing any evidence of additional studies or tests of Cymbalta — such as additional studies comparing

[5] As this Court noted in *Torkie-Tork*, 757 F. Supp. 2d at 573, the Supreme Court of Virginia has repeatedly applied the reason-to-know standard. *See Watson*, 413 S.E.2d at 634-35; *Funkhouser v. Ford Motor Co.*, 736 S.E.2d 309, 313 (Va. 2013); *Jones v. Ford Motor Co.*, 559 S.E.2d 592, 600 (Va. 2002); *Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 366 (Va. 1979); *see also Russell v. Wright*, 916 F. Supp. 2d 629, 651 (W.D. Va. 2013) ("[A] manufacturer's duty to warn of a product's dangers imposes no underlying duty to conduct additional studies or tests because a failure-to-warn claim rests on a *reason-to-know* standard rather than the broader *should-have-known* standard." (quoting *Torkie-Tork*, 757 F. Supp. 2d at 572, and citing *Watson*, 413 S.E.2d at 634-35)) (emphases in original); *Fields v. Jobar Int'l, Inc.*, 2014 WL 1513289, at *4 (E.D. Va. Apr. 16, 2014) ("And, as the [Supreme Court of Virginia] reiterated in [*Watson*], '[a]s we said in *Featherall*, the appropriate standard in Virginia is whether a manufacturer has a *reason to know*, not whether the manufacturer *should know*[.]'" (quoting *Watson*, 413 S.E.2d at 634-35)) (emphases in original).

abrupt discontinuation to tapered discontinuation, studies of particular tapering regimens, studies of longer discontinuation periods, or the use of discontinuation symptom checklists in clinical trials — that Lilly theoretically could have performed, but which FDA did not require as part of the approval process for Cymbalta. Under Virginia's reason-to-know standard, *see, e.g.*, *Watson*, 413 S.E.2d at 634-35, Lilly had a duty to adequately warn Plaintiffs' prescribing physicians of what it knew (or had reason to know) about discontinuation symptoms based on the science *as it existed* — and *not* on how the science theoretically *might* have existed if Lilly had performed the additional studies or tests Plaintiffs have proposed. *See Torkie-Tork*, 757 F. Supp. 2d at 573 ("The only dangers for which Wyeth had a duty to warn adequately are those dangers which Wyeth knew or had reason to know existed based on the science available at the time the product left Wyeth's hands."). Evidence of any such studies is irrelevant to Plaintiffs' failure-to-warn claims under Virginia law and is therefore inadmissible under the Federal Rules of Evidence. *See id.* at 572-73; Fed. R. Evid. 401; Fed. R. Evid. 402.

In these cases, the speculative nature of Plaintiffs' failure-to-test arguments reinforces their irrelevance and inadmissibility. Although Plaintiffs have imagined examples of additional tests that Lilly theoretically could have conducted, Plaintiffs have come forward with *no evidence* that links those hypothetical tests to their claims: they have no evidence of what the results of such tests might have been, no evidence of how such results might have impacted Cymbalta's physician warnings, and no evidence of how any revised warnings might have caused their physicians to alter their prescribing decisions. Indeed, unlike the plaintiff in *Torkie-Tork*, who was at least able to point to a later breast cancer study conducted by the National Institutes of Health that the manufacturer theoretically could have conducted earlier on its own, Plaintiffs have no evidence at all of what their proposed studies might have shown. *See Torkie-*

Tork, 757 F. Supp. 2d at 571-73 (finding failure-to-test evidence inadmissible even though plaintiff was able to point to results of later study defendant theoretically could have conducted earlier). Such raw speculation has no place in a jury trial. *See, e.g., Sakaria v. Trans World Airlines*, 8 F.3d 164, 172-73 (4th Cir. 1993) ("In a long line of decisions in this circuit, we have emphasized that proof of causation must be such as to suggest 'probability' rather than mere 'possibility,' precisely to guard against raw speculation by the fact-finder.") (citations omitted).

It appears that Plaintiffs will attempt to circumvent this legal authority by arguing that their claim is not that Lilly should have conducted additional studies of Cymbalta, but rather that the company should have differently designed the tests it *did* conduct to collect additional data on discontinuation symptoms. *See* Pls.' Opp'n to Def.'s Mots. for Summ. J., July 10, 2015 (Dkt. No. 133 (*Ali*)), Dkt. No. 121 (*Hagan-Brown*)) at 14 n.6 (suggesting that Lilly should have designed its tests to facilitate additional "collection of data" pertaining to discontinuation). This re-casting is a distinction without a difference. Whether framed as a failure-to-test argument or as a should-have-tested-differently argument, the basic thrust of Plaintiffs' position is the same: according to Plaintiffs, Lilly should have taken additional (or different) steps in its Cymbalta studies, and those steps — which FDA indisputably did not require — would have resulted in a different body of science on the risk of discontinuation symptoms. This argument necessarily rests on the assumption that Lilly *should have known* about speculative risk information it could have uncovered only by taking steps to produce additional science that did not exist at the relevant time. As this Court explained in *Torkie-Tork*, this is the very *should-have-known* standard that the Supreme Court of Virginia rejected in *Watson*. *See Torkie-Tork*, 757 F. Supp. 2d at 572-73 (citing *Watson*, 413 S.E.2d at 634-35). Plaintiffs' anticipated counter-argument thus fails to overcome Virginia's prohibition against evidence of alleged failure to test.

Plaintiffs are also likely to point to e-mails or other documents from which they will argue that Lilly employees discussed hypothetical clinical trials, possible alternative testing methodologies, or methods used with other medicines. Plaintiffs likely will further argue that Lilly thus had a "reason to know" about the alternative tests or test designs that Plaintiffs claim Lilly should have conducted or used. But the *Torkie-Tork* plaintiff made the same argument, i.e., that Wyeth had reason to know of the breast cancer risk at issue in that litigation, and this Court appropriately rejected it. In *Torkie-Tork*, this Court made clear that a manufacturer's duty to warn is limited to knowledge of risks "based on the *science* available at the time the product left [the manufacturer's] hands." *Torkie-Tork*, 757 F. Supp. 2d at 573 (emphasis added). The Court's reasoning in *Torkie-Tork* applies equally here. The evidence that Plaintiffs are likely to reference contains no actual scientific results pertaining to Cymbalta — a necessary prerequisite for the evidence to be relevant (and thus admissible) under Virginia's reason-to-know standard.

In short, Plaintiffs seek to impose on Lilly a non-existent duty to conduct additional testing (that FDA did not require) to generate a body of speculative new science that, according to Plaintiffs, should have resulted in different (but unspecified) discontinuation warnings for Cymbalta. The law rejects this argument. Before Lilly brought Cymbalta to market, it subjected the medicine to a rigorous testing protocol consisting of dozens of clinical trials over many years, followed by FDA's searching review and approval process. Any evidence that Lilly could (or should) have conducted hypothetical additional testing is purely speculative and irrelevant under well-established Virginia law. *See, e.g.*, *Ball*, 963 F. Supp. 2d at 506 (under Virginia law, pharmaceutical manufacturer does "not have a duty to conduct additional testing of its product beyond what was performed as part of the FDA approval process"). Such evidence must therefore be excluded.

II. Failure-to-Test Evidence Would Unfairly Prejudice Lilly and Confuse the Jury.

Even if Plaintiffs' purported failure-to-test evidence retained some residual probative value — and it does not — it would still be inadmissible under Federal Rule of Evidence 403. *See* Fed. R. Evid. 403 (court may exclude relevant evidence if probative value is substantially outweighed by danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence"); *see also, e.g.*, *Smithers v. C & G Custom Module Hauling*, 172 F. Supp. 2d 765, 775-76 (E.D. Va. 2000) (granting motions *in limine* where "any possible probative value [was] substantially outweighed by a danger of unfair prejudice, confusion of the issues, or misleading of the jury") (citation and quotation marks omitted). As an initial matter, such testing-related evidence would introduce confusion (particularly in light of its speculative nature) and distract the jury from the core inquiry in these cases — namely, whether Lilly adequately warned Plaintiffs' prescribers of known risks of discontinuation symptoms associated with Cymbalta use. In addition, the introduction of such evidence, combined with Lilly's subsequent rebuttal, would unnecessarily prolong the trials in these cases.

Moreover, the introduction of purported failure-to-test evidence would be unfairly prejudicial to Lilly, as Plaintiffs would use the evidence to paint Lilly in a bad light and suggest — inaccurately — that Lilly had ignored a non-existent duty to engage in endless study of Cymbalta when, in fact, Lilly thoroughly and proactively studied discontinuation symptoms in dozens of clinical trials without FDA raising concerns regarding the methodologies used by Lilly in those trials. The resulting prejudice would far outweigh any minimal relevance that speculative failure-to-test evidence might have with respect to Plaintiffs' failure-to-warn claims. Accordingly, even if the Court were to conclude that evidence of hypothetical additional testing were somehow minimally relevant to Plaintiffs' failure-to-warn claims, the dangers of unfair

prejudice, confusion, distraction, and waste of time would nevertheless counsel in favor of exclusion.

CONCLUSION

For the foregoing reasons, Lilly respectfully submits that the Court should enter an order precluding Plaintiffs from arguing — or from introducing any documents, testimony (live or videotaped), or other evidence to show — that Lilly could (or should) have:

- Used elicited scales or discontinuation symptom checklists in its clinical trials for Cymbalta;
- Conducted additional (or different) clinical trials to assess discontinuation-emergent adverse events beyond two weeks post-discontinuation;
- Conducted additional (or different) studies to assess the benefits of tapering or certain tapering schedules, including studies comparing abrupt versus tapered discontinuation;
- Conducted additional (or different) studies comparing discontinuation symptoms in Cymbalta patients with patients taking other medicines, including Prozac, Paxil, and Effexor;
- Conducted additional (or different) studies assessing other doses of Cymbalta; and/or
- Conducted any additional (or different) testing, studies, or assessments of any kind beyond those that FDA required to secure the medicine's approval.

Dated: July 29, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of July, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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